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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,388	02/10/2004	Jonathan Gressel	27084	1970

7590

11/01/2006

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,388

Applicant(s)

GRESSEL ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/889,737.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 19 October 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's election without traverse of Group I in the reply filed on 09 August 2006 is acknowledged. Claims 1-8 are examined in the Office action that follows. Claims 9-16 are withdrawn as being drawn to a non-elected invention.

The specification is objected to on page 1 for not reflecting the abandoned status of the parent U.S. application. All amendments to the specification should comply with 37 CFR 1.121(b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring "mitigating genetic traits" which are deleterious to weeds, including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or non-flowering; but which mitigating traits are "benign or advantageous when expressed in the commercially

cultivated crop" (see, e.g., page 51 of the specification, lines 14-17). The claims are also drawn to methods of using these constructs to transform plants.

In contrast, the specification provides no guidance regarding the isolation of any protein (or other gene product) from any source or of any sequence which could confer any of the above "mitigating" traits. The single exemplified dwarfism trait was deleterious to the cultivated crop, as discussed below. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or gene products.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring "mitigating" traits which are "benign or advantageous" to cultivated crop plants but deleterious to weeds, including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or non-flowering. The claims are also drawn to methods of using these constructs to transform a multitude of plants of a multitude of species, to obtain a multitude of deleterious phenotypes in a multitude of weedy species and a multitude of benign or beneficial phenotypes in a multitude of cultivated crop species.

In contrast, the specification provides no guidance regarding the isolation of any protein (or other product) from any source or of any sequence which could confer any of the above traits. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or other gene products. No guidance is presented regarding crop plant transformation and the evaluation of the putative genes to confer traits which are "benign or advantageous" to the commercially cultivated crops. Finally, no guidance is provided regarding the identification of any weedy species or transformation therewith to confer a deleterious trait thereto.

The claimed process is hampered by the lack of currently available isolated genes which encode any or all of the proteins involved in the pathways responsible for traits deleterious to weeds (or which modify traits in a manner which would be deleterious), such as secondary dormancy, seed shattering and bolting (see, e.g., Gressel, 1999 Tibtech, page 365, column 1, top and fourth paragraphs, and paragraph bridging the columns).

Moreover, the unpredictability inherent in the process is demonstrated by Al-Ahmad et al (2004, Applicant submitted), who teach that *cultivated tobacco* transformation with a construct encoding gibberellic acid insensitivity conferring a dwarfing “mitigating” trait resulted in the *deleterious* effects of tobacco plant death or greatly reduced flowering (see, e.g., page 697, Abstract). In contrast, Applicant’s definition of “mitigating” as “benign or advantageous when expressed in the commercially cultivated crop” was not obtained.

Furthermore, what constitutes a “weed” is variable and crop-species dependent, as well as temporally-dependent. For example, Desplanque et al teach that plants of the cultivated beet species may be considered “weeds” when they are volunteers which have resulted from seed left in the field the previous season, which arose from mutations in the crop species which facilitated bolting (see, e.g., page 562, column 1 and paragraph bridging the columns).

In addition, what constitutes a trait which is deleterious to a weed (or which is benign or valuable to a crop species) will depend upon the particular crop plant species and the particular weed species, as well as fluctuating environmental stressors.

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Desplanque et al teach that bolting, rather than being deleterious as claimed in claim 3, is an attractive trait for weed beets and their wild relatives, since it facilitates seed propagation and introgression of valuable agronomic traits such as herbicide resistance into the weeds (see, e.g., page 566, column 2, third full paragraph; page 567, Figure 2 and column 2; page 568, column 1, top two paragraphs). Bartsch et al teach that the gene encoding the BNYVV coat protein is beneficial to the sugar beet crop species in the presence of high levels BNYVV infection, but deleterious to the crop species in the presence of low viral infection levels (see, e.g., pages 143-144; page 146, column 1, first full paragraph).

Modification of “deleterious” traits, such as seed coat-influenced uniform germination, is unpredictable, given the lack of understanding of the inheritance of such traits. Linder teaches that the weedy trait of non-uniform germination, thought to be seed coat-influenced and thus maternally inherited, was not maternally transmitted by the weedy *Brassica rapa* when used as the female parent (see, e.g., page 1181, column 2, first full paragraph; page 1183, column 2, second full and bottom paragraphs; page 1186, column 2, first full paragraph; paragraph bridging pages 1189 and 1191). This unpredictable result was also observed by Landbo et al in the weed *Brassica campestris* (see, e.g., page 212, Table 2; page 213, paragraph bridging the columns, column 2, first and second full paragraphs; page 214, column 2, first full paragraph).

Measurement of “deleterious” traits is also unpredictable, given the effects of environment on their expression, and the possible failure of workers to evaluate plants

under these conditions; and given the different expression of transgenes in different genetic backgrounds (see, e.g., Linder, page 1193, column 2, bottom paragraph).

Genetic modification of traits such as seed shattering is unpredictable, due to low heritability, high environmental influence, and the effects of transformation itself. Young teaches that seed shattering in Kleingrass is not highly heritable (see, e.g., page 1156, Abstract). Thus, attempts to either isolate the genes responsible or to modify the seed shattering trait in either the crop species or a wild relative would appear to be difficult. Oard et al teach that seed shattering in cultivated and weedy rice species is highly environmentally influenced, as well as being influenced by the genetic background of the plant, and that the act of transformation with a gene not involved in shattering may still affect the shattering trait (see, e.g., page 14, paragraph bridging the columns, column 2, first full paragraph; page 15, paragraph bridging the columns and Table 1; page 19, column 2, bottom paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of genes conferring benign or valuable traits to a multitude of cultivated crop species transformed therewith, but conferring deleterious traits to a multitude of weedy species transformed therewith.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/34088 (COLD SPRING HARBOR).

The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait including herbicide resistance linked to a gene encoding a second endogenous trait, which second trait is benign to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes non-flowering.

COLD SPRING HARBOR teach dicot or maize plant transformation with a genetic construct comprising a first gene encoding herbicide resistance linked to a second gene encoding antisense *ld* mRNA, wherein plants with absent flowers were produced, and wherein the *ld* gene and its loss-of-function mutant is endogenous to maize (see, e.g., Figures 11A-D; page 7, line 14 through page 8, line 19; page 19, lines 11-19; page 21, line 35 through page 23, line 15; page 27, line 21 through page 28, line 5; page 30, line 22 through page 31, line 29).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al.

Wang et al teach *Arabidopsis* plant transformation with a genetic construct comprising a first gene encoding herbicide resistance linked to a second endogenous *Arabidopsis* gene encoding CCA1 protein, wherein plants with absent flowers (when

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compared to control plants of the same age) were produced (see, e.g., page 1208, column 2, bottom paragraph; page 1209, Figure 2; paragraph bridging pages 1214 and 1215).

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent 5,948,956 filed 16 October 1997).

The claims are drawn to methods for transforming cultivated crop plants with a first gene encoding herbicide resistance and a second gene encoding male sterility or dwarfism.

Lee et al teach methods for transforming cultivated turfgrass plants with a first gene encoding herbicide resistance and a second gene encoding male sterility or dwarfism (see, e.g., column 6, lines 17-26; column 9, line 44 through column 11, line 44; claims 1 and 15-17).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42326 (MOGEN INTERNATIONAL) in view of Christou et al (U.S. Patent 6,114,603 filed 27 March 1998).

The claims are drawn to sugarbeet transformation with a first gene conferring herbicide resistance and a second gene conferring antibolting.

MOGEN INTERNATIONAL teach cultivated sugarbeet transformation with a trehalose-6-phosphate phosphatase (TPP) gene, wherein said gene conferred antibolting to lettuce and thus would inherently confer antibolting to the biennial sugarbeet (if evaluated over two growing seasons), wherein antibolting is desirable for directing biomass to non-reproductive harvested structures; and also suggest the use of an herbicide resistance gene such as a bialaphos resistance gene for a selectable marker (see, e.g., Figures 19 and 21-22; page 8, lines 25-27; page 9, lines 1-11; page 24, lines 3-18; page 27, lines 10-15; page 35, lines 23-27; page 61, line 18 through page 62, line 23; page 72, line 11 through page 73, line 5; and page 148, claims 81-82).

MOGEN INTERNATIONAL does not actually teach sugarbeet plants transformed with a gene conferring bialaphos resistance.

Christou et al teach sugarbeet transformation with a gene conferring bialaphos resistance (see, e.g., claims 1-3 and 8-11).

It would have been obvious to one of ordinary skill in the art to utilize the method of sugarbeet transformation with an antibolting gene as taught by MOGEN

INTERNATIONAL, and to modify that method by incorporating the bialaphos resistance gene taught by Christou et al, as suggested by MOGEN INTERNATIONAL.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/30162 (FORBIO RESEARCH) in view of Boudet et al (U.S. Patent 5,451,514).

The claims are drawn to methods of tree transformation with a first gene conferring modified lignin and a second gene conferring tapetum-specific expression of a cytotoxic gene.

FORBIO RESEARCH teaches eucalyptus tree transformation with a gene comprising a tapetum (part of the stamen, a male flower part) – specific promoter operably linked to a structural gene encoding the cytotoxin barnase, wherein male-sterile eucalyptus trees were produced, in order to produce more harvestable timber without diverting resources to flowers and seedlings; and also teaches that other genes conferring other agronomically useful traits may be employed (see, e.g., page 1, lines 11-17; page 2, lines 6-12; page 3, line 30 through page 4, line 3; page 4, line 17 through page 5, line 5; page 5, lines 20-21; page 8, lines 5-16; page 32, line 8 through page 37, line 12).

FORBIO RESEARCH does not teach eucalyptus transformation with a gene conferring modified lignin.

Boudet et al teach the isolation of a eucalyptus gene encoding an enzyme involved in lignin synthesis, and genetic constructs comprising the gene in antisense orientation with respect to a plant promoter, wherein eucalyptus tree transformation

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therewith would advantageously lead to modified or reduced lignin content for improved timber quality and paper production (see, e.g., column 1, lines 44-49; column 3, line 44 through column 4, line 25; column 5, lines 35-54; and claims 1-6 and 9-12).

It would have been obvious to one of ordinary skill in the art to utilize the method of eucalyptus transformation with a male-specific promoter operably linked to a cytotoxin gene as taught by FORBIO RESEARCH, and to modify that method by incorporating a gene modifying lignin content as taught by Boudet et al, as suggested by each reference. Choice of available male organ-specific promoter would have been the optimization of process parameters.

Claims 5-6 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated gene whose product confers gibberellic acid insensitivity which is benign to cultivated crop plants, or plants transformed therewith; and the failure of the prior art to teach or reasonably suggest corn transformation with a gene encoding a pharmaceutical protein in combination with a mutant shrunken seed gene expressed endosperm-specifically.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 27, 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'D. Fox', written over the printed name and title.